



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/736,419 | 12/15/2003 | Johannis Gillissen | 01901- P0005A | 3982 |
| 24126 | 7590 | 03/13/2006 | EXAMINER | |
| ST. ONGE STEWARD JOHNSTON & REENS, LLC | | | KAUFMAN, JOSEPH A | |
| 986 BEDFORD STREET | | | ART UNIT | |
| STAMFORD, CT 06905-5619 | | | PAPER NUMBER | |
| | | | 3754 | |
| DATE MAILED: 03/13/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

e

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/736,419 | Applicant(s) GILLISSEN ET AL. | |
| | Examiner Joseph A. Kaufman | Art Unit 3754 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1. ☒ Certified copies of the priority documents have been received.
 - 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Graf et al (US 5,257,726) in view of Hansen et al (5,836,922).

Referring to claim 1, Graf et al discloses a dispenser for administration of a pharmaceutical fluid (fig 2) through manual actuation (col 5, lines 21-27) comprising:
--a main body (5, fig 2), which includes an actuator (36, fig 2) mounted movable relative to the main body by means of an actuation force (depression of thumb button) and having an actuation surface (37) which is sufficiently wide to support an average human thumb (col 4, line 68), -- and two grips (6, fig 2) extending from the main body (5, fig 2). Graf et al. lacks providing sufficient room beneath the grips for accommodating one or more fingers that are not employed during actuation, the grips having a top surface which is concave, the actuation force being less than 50N and the actuation surface having a width of at least 2 cm. Hansen et al however discloses sufficient room beneath the grips (fig 4) wherein each of the grips (19) has a top surface which is concave (surface 19, fig 4).

It would have been obvious to one of ordinary skill in the art to have modified the grips of Graf et al with concave grips with having sufficient room beneath in order to comfortably manipulate the device as taught by Hansen et al. It would further have been obvious to configure the actuation device so that the user does not have to apply very much force to actuate in order for the user to comfortably use it multiple times. Finally, providing the actuation surface with a width of at least 2 cm would have been obvious in order to accommodate a person with larger fingers/thumbs.

Referring to claim 2, Graf et al further discloses the actuation surface (37) is sufficiently wide to support one average human thumb (col 4, line 68). As shown in figure 2 the shallow recess 37 is for one thumb and uses up only half of the surface 16 at the bottom of the dispenser hence it would be capable of applying adequate force on surface 16 with one hand, it is capable being operated by two hands. It would be obvious to use both hands to operate the dispenser for a patient suffering from arthritis so the less pressure is applied on each thumb of the hand and make the device easier to use.

Referring to claim 3, Graf et al further discloses a radius of curvature of the edge along the actuation surface (36) and/or of the top edge along the grips (end of 6, fig 2) but does not disclose it is in excess of 3 mm. Although the dispenser of Graf et al appears to show the radius of curvature as being 3mm, it would have been obvious to

provide the actuation surface with a radius of curvature in excess of 3mm in order to reduce the pressure on hands of the user.

Referring to claim 4, Graf et al further discloses the actuation surface is provided with a shallow recess (37) for accommodating an average human thumb (col 4, line 68).

Referring to claim 5, Graf et al discloses the cross-section of the actuator (fig 2) and that part of the main body (5, fig 2) in which the actuator (36) is mounted is oblong (fig 2).

Referring to claim 6, Graf et al further discloses the actuator (36) and the main body (5, fig 2) are provided with co-operating guiding features (9, inner sleeve, fig 2) extending in the direction of actuation.

Referring to claim 8, Graf et al further discloses the actuator (36, fig 2) wherein the center of gravity is located in the lower half of the dispenser (fig 2, feature 36 placed in lower half of dispenser 5).

Referring to claim 9, Graf et al further discloses a dispenser for administration of a pharmaceutical fluid (fig 2) through manual actuation, at least comprising a main body (5), having an elongated nozzle (7) located on the axis of symmetry of the dispenser comprising two radially extending shoulders forming grips (surfaces 6), a cup shaped

Art Unit: 3754

actuator (36, fig 2) mounted movable relative to the main body (5) and having an actuation surface (37) which is sufficiently wide to support an average human thumb (col 4, line 68), the bottom of the actuator having a shallow concave recess (37) with curved rounded edges (fig 5, 15b), the lower section 5b, fig 5) of the main body having a thin outer wall of substantially oblong cross section (fig 5) with slightly convex walls (40b) and rounded corners (end of surfaces 3b, fig 5) having a radius of curvature which seems to be least 4mm but does not disclose the top surface of the extending shoulders being at least 15mm wide and the top surface of the shoulders being concave with a radius of curvature between 25 to 40 mm and the radius of curvature of the top edge along the grips is in excess of 3mm, the bottom of said grips at least partially defining an area for accommodating one or more fingers, distance between top surface of the shoulders and the bottom surface of the actuator being between 50 to 55 mm. Hansen et al discloses the surface of the shoulders (19) being concave with a radius of curvature which seems to be in the range of 25 to 40mm and discloses the bottom of grips having a defined area for accommodating a finger (19, fig 4) and radius of curvature of the top edge along the grips seems to be in excess of 3mm.

It would have been obvious to one of ordinary skill in the art to have modified the surface of the shoulders and grips of Graf et al with concave shoulders and grips of Hansen in order to comfortably manipulate the device as taught by Hansen et al. Since larger the contact surface of the actuation device, the easier to actuate device, it would be obvious to size surface to so the average hand is comfortable during use in order to assure excessive pressure is not applied by the hand. Finally, providing the actuation

surface with a width of at least 2 cm would have been obvious in order to accommodate a person with larger fingers/thumbs.

Referring to claim 10, Graf et al further discloses a dispenser for flowable pharmaceutical media but does not disclose it contains a pharmaceutical fluid for treating rheumatoid arthritis. It would have obvious to one of ordinary skill in the art to have assumed any pharmaceutical fluid as well as treatment for rheumatoid arthritis can be contained in this dispenser.

Response to Arguments

3. Applicant's arguments filed 12/30/2005 have been fully considered but they are not persuasive.

Applicant's arguments regarding the newly claimed width of the support surface are moot in view of the new grounds of rejection.

Applicant contends that Graf et al. teaches the use of a small device that would not support such a large support surface. Using the quote cited by applicant's representative, while the device "can be kept very small", it is not required to be small.

Applicant contends that there would be no need to modify the grips of Graf et al. with those of Hansen et al. as those of Graf are already wide enough to accommodate fingers. However, applicant has not addressed the motivation repeated above that employing a curvature would add comfort to the user.

Regarding that Hansen et al. would "only provide grips if 'sufficiently great contact surface is not present'" does not preclude the use of additional motivation that has been provided for the modification.

Applicant contends that the device of Graf et al. is only for a single thumb. Given that the size of people's thumbs vary greatly, this argument is not persuasive. Further, motivation has been provided along these lines for the 2 cm requirement now present in the claims.

Applicant contends that the actuation surface is not oblong. As a non-perpendicular cross section would yield an oblong surface, the claimed limitation is met.

Finally, as the portions disclosed above act to guide the actuation of the device, the claimed limitations are met. The various rib structures disclosed by applicant are beyond the scope of the claims.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any


Art Unit: 3754

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph A. Kaufman whose telephone number is (571) 272-4928. The examiner can normally be reached on Monday-Thursday, 5:30AM-2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Mar can be reached on (571) 272-4906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Joseph A. Kaufman
Primary Examiner
Art Unit 3754

3/6/06

jak
March 6, 2006